

Title: **Quality Control Record Sheet**
3 Screen ICA ELISA Kit QC Data

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 Revision: **3**
 Date: **07/09/18**
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Prepared by: **G Flood**
 Approved by: **F Ryrie**

Kit lot number: **KZGIE51A** Kit expiry date: **01st May 2021**

Reagent Lot Numbers:

3 Screen Coated Wells:	ZGIE32	Expiry date:	01 Dec 2021
3 Screen-Biotin:	ZGIB19e	Expiry date:	01 Nov 2021
Recon. Buffer for 3 Screen-Biotin:	3BB14	Expiry date:	15 Sep 2021
Streptavidin Peroxidase:	GEP356	Expiry date:	17 Aug 2021
Diluent for SA-POD:	PB156	Expiry date:	03 Feb 2022
Peroxidase Substrate:	PTS169B	Expiry date:	17 Feb 2022
Stop Solution:	HESP106	Expiry date:	02 Jun 2022
Concentrated Wash Solution:	CW242	Expiry date:	10 Aug 2022
Reference Preparation:	ZGIR32	Expiry date:	01 Oct 2021
Calibrators:	ZGIC32	Expiry date:	01 Oct 2021
Negative Control:	ZGIN32	Expiry date:	01 Oct 2021
GAD Ab Positive Control:	3SGP32	Expiry date:	01 Oct 2021
IA-2 Ab Positive Control:	3SIP32	Expiry date:	01 Oct 2021
ZnT8 Ab Positive Control:	3SZP32	Expiry date:	01 Oct 2021

Curve and Controls: Incubation temp: **22** °C

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.081	0.025
Calibrator 15 units per mL	0.157	0.049
Calibrator 100 units per mL	0.700	0.221
Calibrator 400 units per mL	2.397	0.761
Calibrator 2000 units per mL	>4	2.278
Reference Preparation	0.716	0.226
Negative Control	0.049	0.015
GAD Ab Positive Control	1.327	0.417
IA-2 Ab Positive Control	0.580	0.182
ZnT8 Ab Positive Control	0.366	0.116

Control	Concentration at 450 nm (units per mL)	Concentration at 405 nm (units per mL)	Range (units per mL)	Index Value at 450 nm	Index Value at 405 nm	Range (index value)
Negative	<5	<5	<5	<30	<30	<30
GAD Ab Positive	212.1	204.2	240±80	185.3	184.5	210±70
IA-2 Ab Positive	79.6	80.7	70±25	81.0	80.5	75±30
ZnT8 Ab Positive	46.0	48.5	45±18	51.1	51.3	52±21

Materials of human origin used in the manufacture of this product have been tested and found non-reactive for HIV1 and 2 and HCV antibodies and HBsAg at the time of testing.

Assay performed by: **Fiona Ryrie**
 Signature: *Fiona Ryrie*
 Position: **Scientific Assistant**
 Date: **09th September 2020**

Authorised by: **DR G Flood**
 Signature: *G Flood*
 Position: **HEAD OF QC**
 Date: **20th Oct 2020**